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09/754,947	01/04/2001	Bruce A. Lee	14907003310	4527

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	9

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/754,947	LEE ET AL	
	Examin r	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election

1. Applicant's election of Group I claims 1-30 drawn to a method of detecting the presence and absence of Bacillus anthracis in Paper No 8, 3/11/02 with traverse is acknowledged. Claims 1-32 are pending in the application. Claims 31-32 have been withdrawn from consideration as drawn to a non-elected invention.

Applicant requests the Examiner to reconsider the restriction and withdraw the restriction requirement and examine all the claims pending in the application. The traversal is on the ground(s) that the search and examination of the entire application can be performed without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. This is not found persuasive because the inventions are distinct and independent and acquired a separate status in the art as a separate subject for inventive effect. The inventions of the group I is drawn to a method of detecting the presence and absence of Bacillus anthracis in a sample and a kit for detecting the presence and absence of Bacillus anthracis while invention of group II is drawn to a recombinant antibody (i.e., product) which specifically binds to an antigenic determinant of surface protein. Since the surface array protein consists of many antigenic determinants, the sequence searches for various antigenic determinants of SEQ.ID.NO: 1 would be different. Hence, the amino termini of heavy and light chain of these antibodies are considerably different and result in an innumerable antibodies (i.e., phage libraries) which could be different from the one being used in the method. Further, the product as claimed could be used in many other utilities as explained in Paper # 7 such as treating the infection etc. A reference, which would anticipate the invention of group I, would not necessarily anticipate or make obvious group II (see paragraph 10 of this Office action, no antibodies are required). Moreover, as to the question of burden of search, classification of

subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues (for example enablement) also exist.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. This application claims priority under 35 U.S.C. 119(e) to a Provisional Application 60/174,901 filed on 1/6/2000 is acknowledged.

Information Disclosure Statement

3. The information disclosure statement filed 4/27/01 (Paper # 4) is acknowledged and a signed copy is attached to this Office Action.

Specification - Informalities

4. Applicant claims priority under 35 U.S.C. 119(e) to a Provisional Application 60/174,901 filed on 1/6/2000. However, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Claim Rejections - 35 USC 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as being vague in the recitation of " detecting whether surface array protein is bound to the capture reagent" It is not clear how one would detect a surface array protein in a sample which is bound to the capture reagent without adding detection reagent to the sample?

Claims 5 and 6 are rejected as being vague in reciting "recombinant". It is not clear to the examiner what are the metes and bounds of a recombinant antibody or recombinant polyclonal antibody? It is not clear whether antibodies are raised against a recombinant protein in an animal or antibodies are constructed using recombinant methodology?

Claim Rejections - 35 USC 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 7, 8,10,11, 13-17,19, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ligler et al 1996, U.S.Patent 5,496,700.

Claims are drawn to a method of detecting the presence or absence of B. anthracis in a test sample using a capture reagent (monoclonal antibody) that binds to B.anthracis surface array protein and a detection agent comprising detectable label.

Ligler et al disclose a method of detecting the presence or absence of B. anthracis in a test sample using a capture reagent that binds to B.anthracis and detection agent comprising detectable label (see abstract and claims). Monoclonal antibodies FDF –IB9, specific for B.anthracis were immobilized on a solid support, fibers (see example 2) as a capture reagent.

Nile red was used as a detectable label that binds to a different epitope on the anthracis spores (see example 2). Clinical samples suspected to have B.anthracis were used in this assay (see example 7). This method detects 3 cells /ul (see abstract and figures1 and 7) and appear to be sensitive. Thus, the prior art anticipated the claimed invention. In the absence of evidence to the contrary the disclosed prior art anthracis spores read on the claimed surface array protein. Characteristics such as amino acid sequence SEQ.ID.NO: 1 would be inherent in the preparations of Ligler since the samples contain encapsulated spores which comprise surface array proteins (examples 2 and 7). Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948).

9. Claims 1-6, 8, 10-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu H 1998, Journal of Immunological Methods, Vol. 218, 1-8.

Claims are drawn to a method of detecting the presence or absence of B. anthracis in a test sample using a capture reagent (polyclonal antibody) that binds to B.anthracis surface array protein and a detection agent comprising detectable label.

Yu discloses two types of solid phase immunoassays for detecting the presence of B. anthracis in a test sample using a capture reagent (see page 3, right column, first paragraph) which is a goat anti anthracis (see abstract). Primary capturing antibodies (goat anti anthracis antibodies), specific for B.antracis were immobilized on a solid support, magnetic bead or 96 well micro plate (abstract). Biotin-streptavidin or alkaline phosphatase or FITC (page 2, left column, fist two paragraphs) labeled antibody was used as a detectable reagent that binds to a different epitope on the anthracis spores since the FITC labeled antibody and goat antibody

coated on to the magnetic bead or 96 well micro plate are different (see page 3, right column, first paragraph) i.e., GT-578 and Gt-5A. Samples suspected to have B.anthracis from blood or environmental water were used in this assay (see abstract). This method detects 100 cfu /ml (see figure 4 and 3.1 under results). Characteristics such as amino acid sequence SEQ.ID.NO: 1 would be inherent in the preparations of Yu since the samples contain encapsulated spores which comprise surface array proteins (examples 2 and 7). Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts). See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948).

10. Claims 1-3 are rejected as being anticipated by Graham et al 1984 (Eur.J.Clin. Microbiol, 3:210-212).

Claims are drawn to a method of detecting the presence or absence of B. anthracis in a test sample using a capture reagent that binds to B.anthracis surface array protein and detecting the presence of surface array protein which is an indication of presence of B. anthracis in a test sample.

Graham et al disclose an Enzyme –Linked Lectinosorbent Assay (page 210-211) for detecting the presence of B. anthracis in a test sample comprising contacting lectins from Glycine max and Helix pomatia which are conjugated to horseradish peroxidase (see abstract and Table 1 and 2). Lectin conjugates are used as capture reagents in this assay. Characteristics such as amino acid sequence SEQ.ID.NO: 1 would be inherent in the preparations of Graham et al since the samples contain encapsulated spores which comprise surface array proteins. Applicant's use of the open-ended term "having " in the claims fails to

exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts). See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948).

Claim Rejections - 35 USC 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

12. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al 1996, U.S.Patent 5,496,700 or Yu 1998, Journal of Immunological Methods, Vol. 218, 1-8 as discussed above and further in view of Litman et al 1983, U.S.Patent 4,391,904.

The Prior art as discussed above does not teach that the reagents antibodies and detection reagent are put together in the form of a kit.

Litman et al teach a kit for use in an immunoassays comprising antibodies and detection reagents for detection of varieties of microorganisms including B.anthracis (abstract, claims and column 30, line29). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep all the ingredients disclosed by the prior art (Ligler et al/Yu) in the form of a compact kit since kits are easy to transport and convenient to work with and does not require trained technicians to perform the test on site. An artisan of ordinary skill would have been motivated in applying the art disclosed by Ligler et al or Yu to keep the reagents together in the form of a kit because kits would help in diagnosing anthracis conveniently and do not require trained technical support since it comes with instructions to use. Although Litman et al did not teach that the samples are collected by cyclonic device, it is well known to a person of ordinary skill in the art of immunology that the air samples would be collected by the disclosed device. Kits were well known in the market for testing or diagnosing varieties of diseases and come with the instructions. Therefore, the claimed invention is prima facie obvious in view of Ligler et al or Yu and further in view of Litman et al absent any convincing evidence to the contrary.

14. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable Phillips et al FEMS Microbiology Immunology 1988, 47: 169-178 in view Toumelin et al 1995 Journal of Bacteriology 1995, 177: 614-620.

Phillips et al teach a method of detecting the presence of B.anthracis spore antigens using polyclonal antibodies (i.e., capture reagent) and monoclonal antibodies in an immunofluorescence (see Materials and methods) and western blot analysis. However, the prior art does not teach that the surface array protein comprises SEQ.ID.NO: 1.

Toumelin et al 1995 teach the characteristics of cell surface protein (surface array protein) by sequencing the structural gene (see Figure 3). The prior art teaches the amino acid sequence of the surface array protein comprising SEQ.ID.NO: 1 (see Figure 3).

An artisan of ordinary skills would have been motivated in applying the teaching of Phillips et al to Toumelin et al with a reasonable expectation because Phillips et al clearly teach the methodology for raising antibodies to spores and the diagnostic methods. Phillips et al teach that the two mouse monoclonal antibodies to spores appear to react with different epitope since monoclonal E12 while reacting with the spores in IF but not in the extracts of the spores in western blot analysis (see Discussion). Further, Phillips et al suggest that investigation of antigen structure is advantageous in analyzing the spore antigens (see page 170, left column, first paragraph) for diagnostic purposes. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the teachings of Toumelin et al 1995 for making cell surface polyclonal antibodies or monoclonal antibodies either in vivo or in vitro using the surface array protein comprising SEQ.ID.NO: 1 and use them for diagnosing B.anthracis in a sample as taught by Phillips et al. The claimed invention is prima facie obvious in view of Phillips et al Toumelin et al absent any convincing evidence to the contrary.

Status of Claims

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

3/26/02

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